

Remarks

Cancellation and Amendment of Claims

In light of the Examiner's remarks and rejections, the Applicants have cancelled claims 53, 63, 87-92 and 94 and amended claims 64, 95, 97 and 98. The Applicants respectfully request the Examiner's review of the amended Claims and previously presented claims 93 and 96. The Applicants affirm that the amended Claims contain no new matter. The Applicants draw the Examiner's attention to the amendments of Claims 97 and 98, which amendments were made solely to correct grammatical and typographical errors, respectively.

The Applicants have reviewed the Examiner's remarks and submit that the Claims presented herein are now in a condition for allowance, particularly in view of the previous Examiner's remark that the claims in the case are "enabling for a nucleic acid encoding 57 amino acid residue T7B peptide linked to the carboxy terminal of a protein of interest under physiological conditions and enhancing the protein's solubility and proper folding in *E. coli*" (see page 5 of the Office Action mailed on August 9, 2005).

In further support of the Applicants' assertion that the Claims are now in condition for allowance, the Applicants offer the following remarks and responses to the Office Action mailed on May 5, 2006.

1. Claim Objections:

Claims 63, 88, 89, and 91 were objected to as being of improper dependent form for failing to limit the subject matter of a previous claim. Via this paper the cited Claims have been cancelled and the Objection is therefore rendered moot. Applicants request withdrawal of the Objection.

2. Rejection under 35 USC 112, second paragraph: indefiniteness:

Claims 53, 63, 87-91 and 94-96 have been rejected as noted.

In response the Applicants have cancelled Claims 53, 63, 87-91, and 94 and have amended Claim 95. Thus the rejection of Claims 53, 63 and 87-91 is moot. In addition, because amended Claim 95 and previously presented Claim 96 now depend from amended Claim 64, which was not rejected under 35 USC 112 second paragraph, the Applicants respectfully submit that these Claims are now in condition for allowance and request withdrawal of this basis of rejection.

3. Rejection under 35 USC 112, first paragraph:

Claims 53, 63, 87-98 have been rejected as noted for failing to comply with the written description requirement.

In response the Applicants have cancelled Claims 53, 63, 87-91, and 94 and have amended Claim 95. The Applicants submit that the rejection of the cited Claims is rendered moot as a result of Applicants' cancellations and amendment. Because amended Claim 95 and previously presented Claim 96 now depend from amended Claim 64, which was not rejected under 35 USC 112 first paragraph, the Applicant respectfully submits that these Claims are now in condition for allowance.

In addition, the Applicants respectfully submit that Claim 93 has been improperly rejected under 35 USC 112, first paragraph. First, Claim 93, as previously amended and re-presented here, is fully supported by the written description with respect to the peptide extensions as the claimed peptide extensions were described in detail as itemized in Table I of the Specification. Thus, the language “comprises the carboxyl-terminal 57 amino acids of the T7 gene 10B protein” was not contained in this claim as originally presented and therefore it is the Applicants’ position that this basis for rejection of Claim 93 is unfounded.

Second, to avoid repetition, the Applicants draw the Examiner’s attention to the remarks below discussing the meaning, to those of skill in the art, of the phrase “consisting essentially of the encoded peptide fused to the carboxy(l)-terminus of the protein polypeptide of interest”. It is the Applicants’ position that “consisting essentially of the encoded peptide fused to the carboxy(l)-terminus of the protein polypeptide of interest” is well understood by those of skill in the art and is fully supported by the written description of the specification.

The Examiner further indicates that the written description does not support a vector optimized for use in “all protozoans”, but that a person of skill in the art would “conclude that the vector is optimized for use in certain bacterial cells”. The Applicants respectfully submit that those of skill in the art are familiar with the various expression vectors that have been optimized for use in various bacterial cells. A person of skill in the art would find it a simple matter to choose a vector optimized for his/her ‘bacterial cells of choice’ and would be extremely unlikely to choose a vector optimized for use in

one host in a different host. Thus, in any system for expression of proteins or polypeptides of interest, vectors optimized for use in particular host cells can be created so that the peptide extensions are encoded in frame with the protein or polypeptide of interest so that the expressed fusion protein includes the peptide extension fused to the carboxyl-terminus of the protein or polypeptide of interest. To use the Examiner's example, if a person of skill in the art developed a vector for use in an extreme halophile, it would be a simple matter for such person to incorporate the coding sequences for the peptide extensions into vector. Thus, expression vectors optimized for use bacterial cells is enabled by the written description since it is only a matter of selection by the person of skill in the art as to which expression host he or she will use.

Therefore, the Applicants respectfully request the Examiner's reconsideration and withdrawal of the rejection under 35 USC 112, first paragraph, written description.

4. Rejection under 35 USC 112, first paragraph, enablement.

Claims 53, 63, 64, 87-98 were rejected as noted.

The Applicants respectfully note that the cancellation and amendments render this rejection moot and request the Examiner's reconsideration and withdrawal of this rejection, particularly with respect to the Examiner's discussion of "comprising the carboxy-terminal of a T7 gene 10B protein".

With respect to the Examiner's remarks on the breadth of the expression "consisting essentially of":

"information is not provide for the limitation of the nucleic acid sequences *consisting essentially of* the encoded peptide fused to the carboxy-terminus of the protein of interest. As "consisting essentially of" may be broadly interpreted to mean the encoded peptide fused to the protein of

interest plus any conceivable possible sequence, then the peptide fusion may include the T7B peptide, the protein of interest [and] any other possible sequence without limitation." (some emphasis added)

the Applicants respectfully submit that a person of skill in the art would find it extremely unreasonable to include "any other possible sequence without limitation" in a construct designed to express a protein or polypeptide of interest. In fact, a person of skill in the art would know that doing so would be counterproductive to the goal of expressing the protein or polypeptide of interest in a soluble, correctly folded state. Further, persons of skill in the art readily recognize that "consisting essentially of" means, for example, the protein or polypeptide of interest, the carboxyl-terminal peptide extension and additional amino acids such as encoded amino acids which may be later cleaved from the expressed protein during processing by the host cell – e.g. during transport to the bacterial periplasm or transport to the medium in the case of proteins that are extruded from the cell or any few encoded amino acids that could not be eliminated from the cloned coding sequence because of cloning difficulties related to lack of restriction sites, etc.. In the present instance, for example, this would encompass the amino acids Lys – Glu – Asp – Pro (LEDP) that are at the N-terminus of each of the encoded peptide extensions of Table I and the claims.

Thus, the Applicants respectfully submit that the Claims presented herein are fully enabled by the specification and request reconsideration and withdrawal of this rejection.

5. Rejection under 35 USC 102(b)

Claims 53, 63, 88, 89, 90, 91, 94, 95 and 96 were rejected as being anticipated by Rechsteiner et al (US 5,366,871).

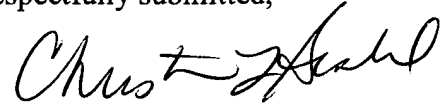
Claims 53, 63, 88, 89, 90, 91 and 94 have been cancelled. Claims 95 and 96 now depend from the non-cited Claim 64. Thus, the Applicants submit that the Claims presently under consideration are not anticipated by Rechsteiner et al.

Summary

Claims remaining under consideration include currently amended Claims 64, 95, 97 and 98 and the previously presented Claims 93 and 96. The amendments of the Claims contain no new matter.

In light of the above Amendments and Remarks, applicants respectfully submit that the instant application is now in condition for allowance and solicit a timely notice of allowance.

Respectfully submitted,



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